UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA and the COMMONWEALTH OF MASSACHUSETTS Plaintiffs, *ex rel.* LISA WOLLMAN, M.D. Plaintiff-Relator, v. THE GENERAL HOSPITAL CORPORATION (d/b/a the Massachusetts General Hospital), THE MASSACHUSETTS GENERAL HOSPITAL'S PHYSICIAN'S ORGANIZATION and PARTNERS HEALTHCARE SYSTEM, INC. Defendants.	**Civil Action 15-11890-ADB** **AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

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I. INTRODUCTION

1. This case concerns the many occasions when MGH orthopedic surgeons, with no disclosure to patients—let alone informed consent—booked two or three surgeries, each lasting three hours or more, for different patients. The surgeries were scheduled to start within 15-30 minutes of one another. This often meant an unwitting patient was left fully anesthetized—unconscious, paralyzed, intubated, dependent on a ventilator to breathe—for longer than medically necessary, often in the care of trainees, without the backup of a properly qualified surgeon, despite legal requirements. Operating surgeons often failed to document adequately their presence for the critical parts of each surgery, as required. These derelictions violate the standards established as a condition of payment by the federal government and the Commonwealth of Massachusetts, including Medicare and Medicaid.

2. This practice became common in 2000 after MGH[1] appointed a new chief of the Department of Orthopaedics ("the Department") and charged him with increasing revenue by the Department: he did this by introducing new financial incentives for the surgeons to generate profits by performing more surgeries.

3. Between 2010 and 2015 Relator, Lisa Wollman, M.D. ("Dr. Wollman") was the treating anesthesiologist for patients whose treating surgeons engaged in concurrent surgeries. She bore witness to patients placed under anesthesia longer than medically necessary and treating surgeons double tasked (or more) without proper backup or the medical record documentation necessary for billing and patient treatment.

[1] The Defendants are: The General Hospital Corporation (d/b/a the Massachusetts General Hospital), ("the Hospital"), the Massachusetts General Hospital's Physician Organization ("MGHPO") and Partners Healthcare System ("Partners") (collectively "Defendants" or "MGH").

4. Dr. Wollman, a highly-respected anesthesiologist with a Medical Degree from Einstein Medical School, brings this *qui tam* case because she believes in the principle enshrined in the American Medical Association's ("AMA") Principles of Medical Ethics that "a physician shall be dedicated to providing competent medical service with compassion and respect for human dignity"; and "a physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception."

5. CMS[2] and Massachusetts regulations provide that the teaching attending physician must be present for the critical or key elements of each surgery. He or she may only leave the first surgery when the key or critical elements *are completed.* (Residents or fellows may finish the non-critical parts.)[3] Surgeries in compliance with this rule are often called overlapping surgeries. Even after the teaching attending has left, CMS requires him/her to have arranged for another qualified surgeon to be immediately available to assist the resident in the first case should the need arise.[4] CMS will not pay for surgeries where the key or critical elements of each surgery take place at the same time (generally called concurrent surgeries). Nor should they; a patient, already anesthetized, should not have to wait for her surgeon to complete the key elements of another surgery.[5]

VIOLATIONS

6. From at least 2006 to the present, Defendants in conspiracy with a core group of

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[2] Centers for Medicare & Medicaid Services ("CMS")

[3] CMS Manual System, Pub 100-04 Medicare Claims Processing (Transmittal 2303) (Sept. 14, 2011) (hereafter "CMS 2011 Claims Manual") at 100.1.2 (Surgical Procedures) A (available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2303CP.pdf, (last viewed on May 16, 2017)); 130 CMR ¶ 450.275(D)(4)(a).

[4] *Id.*

[5] As noted on its website -- http://www.massgeneral.org/overlapping-surgery/about.aspx -- MGH continues to mislead the public and patients by conflating concurrent and overlapping surgeries which are not the same as explained by CMS guidance.

orthopedic surgeons working at MGH, caused the submission of false claims for reimbursement to government payers, in violation of the federal False Claims Act and the Massachusetts False Claims Law.[6] Specifically, Defendants billed or caused others to bill public payers for surgeries that do not conform in material respects to Medicare and Medicaid rules designed, *inter alia*, to protect patient safety. These violations caused improper billing of Medicaid and Medicare for concurrent surgeries in which:

- the patient's surgeon – the teaching physician – is not present during the majority of the surgery, including the "key and critical" portions;
- the patient is left alone with a resident or fellow during surgery at times when his/her surgeon is involved in another surgery *and* no other qualified teaching physician is made immediately available to assist, if needed or in time of emergency;
- the patient is administered anesthesia, which is not medically reasonable or necessary, while waiting – sometimes for an hour or more – for his/her surgeon (the teaching physician) to conclude work in another surgery and scrub in;
- the patient has not given valid consent to the concurrent surgery because MGH's written informed consent documents fail to mention that the surgeon will be involved in another surgery at the same time;
- the surgeon has failed to appropriately document concurrent surgeries; and
- Defendants knew (and still know) that they have been overpaid by Medicare and Medicaid in connection with the unlawful requests for payment, but have not taken appropriate steps to satisfy obligations owed to government payers.

7. Virtually every concurrent surgery MGH billed to Medicare and Medicaid is marked (and compromised) by at least one or more of the violations detailed above because MGH's policies and practices – driven by the desire to increase profits – ensure that such derelictions occur including, but not limited to:

- encouraging and/or failing to discipline teaching or attending physicians who bill government payers when they are not present during the majority of the surgery nor readily available when residents or fellows are performing the surgery;

[6] 31 U.S.C. § 3729 *et seq.* and M.G.L. c. 12, § 5B *et seq.* (respectively).

- failing to ensure that another teaching physician is available to assist patients when they are left alone with a resident or fellow during concurrent surgeries;

- designing patient consent forms which conceal facts regarding the surgeon's decision to conduct two or more surgeries at the same time;

- encouraging, ignoring, and/or failing to audit patient charts for false attestations by teaching physicians, used to support false billing statements;

- adopting hospital rules in 2012, which were purportedly designed to address the concerns expressed by members of the Medical Staff about the practice of booking concurrent surgeries and leaving trainees without appropriate supervision by a teaching surgeon and to curb billing abuses, but which instead largely ratified the unlawful practices;

- ignoring, marginalizing, retaliating against or forcing out physicians, including Relator, who complained about MGH's practice of double or triple booking, including patient harm caused by such practices;

- providing monetary rewards for physicians who engage in concurrent surgery; and

- suppressing an internal investigation conducted by MGH about the above unlawful practices.

8. In sum, these intentional and systemic failures caused and continue to cause Defendants routinely to submit false claims for surgeries and unreasonable and unnecessary anesthesia services to be billed to government payers, which pay for a significant proportion of orthopedic surgeries annually. MGH orthopedic surgeons performed surgery on many Medicare and Medicaid patients.[7]

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[7] Nationally, Medicare was the primary payer for 63.3% of all total knee replacements and 58.2% of total hip replacements in 2000, 54.7% of total knee replacements and 52.8 percent of total hip replacements in 2009. See, American Academy of Orthopedic Surgeons press release, March 14, 2014, *2.5 Million Americans Living with an Artificial Hip, 4.7 Million with an Artificial Knee*, at http://newsroom.aaos.org/media-resources/Press-releases/25-million-americans-living-with-an-artificial-hip-47-million-with-an-artificial-knee.htm (last viewed April 24, 2017). Something like 22% of those aged 65 and over (far more than younger people) develop (shoulder) rotator cuff tears, many of which require surgical repair. Lauren Wessel, Joshua Sykes, Jason B. Anari, and David Glaser, *Indications and Techniques for Double-Row*

9. Had federal, state, and other government sponsored employee health care programs known that MGH's surgical procedures, as outlined above, were not eligible for reimbursement, they would not have reimbursed Defendants for such procedures.

10. In order to redress the violations, on behalf of the United States of America and the Commonwealth of Massachusetts, Relator Dr. Wollman brings this *qui tam* Amended Complaint against Defendants alleging federal and state false claims act violations arising from orthopedic surgical services provided to patients at MGH who are/were eligible to receive health care coverage provided by publicly funded insurance plans, including Medicare, Medicaid, Tricare and state employee health care plans (collectively "government payers" or "government health plans").

II. PARTIES

11. Relator Lisa Wollman, M.D., is a citizen of the Commonwealth of Massachusetts. She is a graduate of the University of Pennsylvania and of the Albert Einstein College of Medicine of Yeshiva University, Bronx, New York, and is licensed to practice medicine in Massachusetts. She is board-certified in Anesthesiology and has practiced medicine as an anesthesiologist since 1990. Relator was in residency training from 1990 to 1993. In 1995, Dr. Wollman received a Certificate of Added Qualifications in Critical Care Medicine. She is the sole or contributing author of several peer-reviewed published papers and book chapters in anesthesiology. From 1993 until February 2015, she was employed as an anesthesiologist by Defendant MGH, in Boston, Massachusetts, and served as faculty (from 1995 to 2015). Relator disclosed the allegations to the government alleged herein prior to filing her initial complaint.

12. Defendant General Hospital Corporation (d/b/a Massachusetts General Hospital)

Fixation, in Elite Techniques in Shoulder Arthroscopy: New Frontiers in Shoulder Preservation 211 (John D. Kelly, IV, ed., 2016).

("the Hospital") is a non-profit corporation, and a Harvard-affiliated teaching hospital, with a stated "commitment to advancing care through pioneering research and educating future health care professionals." MGH is "the largest teaching hospital of Harvard Medical School" and it touts its work to "prepare [] future health care professionals and train [] providers in innovative therapies." It offers "specialized residencies in each of its multidisciplinary care centers and clinical departments."[8] As for its clinical work, MGH states that it "offers sophisticated diagnostic and therapeutic care in virtually every specialty and subspecialty of medicine and surgery ... in four health centers in the Boston area."[9] For many decades, MGH has held itself out to the public as a center of excellence. MGH works with its physician's organization, the Massachusetts General Physicians Organization, to bill for clinical services and compensate members of its Medical Staff, who often are technically employed by the MGPO. MGH's principal address is 55 Fruit Street, Boston, Suffolk County, Massachusetts 02114.

13. Defendant the Massachusetts General Physicians Organization ("MGPO") is a private corporation organized under the laws of the Commonwealth of Massachusetts, located at 55 Fruit Street, Boston, Suffolk County, Massachusetts 02114, and, at times relevant to this action, David Torchiana, M.D. served as its Chairman and Chief Executive Officer. In March of 2015, Dr. Torchiana became the President and CEO of MGPO. On information and belief, also at times relevant, Peter Slavin, M.D., served on the MGPO's Board of Directors. On information and belief, working with MGH, the MGPO was and is instrumental in billing for medical services and compensating members of the Medical Staff at MGH.

14. Defendant Partners Healthcare System, Inc. ("Partners") is a non-profit

[8] See www.massgeneral.org/education/default.aspx.
[9] http://www.massgeneral.org/about/overview.aspx.

corporation, with a principal address at 800 Boylston Street, Suite 1150, Boston, Suffolk County, Massachusetts 02199. According to its 2013 filing with the Massachusetts Health Policy Commission, Partners is the parent organization of an integrated health system founded by Brigham and Women's Hospital and Massachusetts General Hospital. In addition to these two academic medical centers, Partners includes community and specialty hospitals, a managed care organization, community health centers, a physician network, home health and long-term care services, and other health-related entities. Relevant here, Partners Office of Graduate Medical Education oversees residency programs, including the Harvard Combined Orthopaedics Residency Program ("HCORP"), at MGH.

III. JURISDICTION AND VENUE

15. Relator brings this action on behalf of herself and the United States for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 and on behalf of the Commonwealth of Massachusetts, pursuant to Mass. Gen. Laws Ch. 12, § 5B *et seq*.

16. This Court has federal subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 and supplemental jurisdiction over the counts relating to Mass. Gen. Laws Ch. 12, § 5B *et seq*. pursuant to 28 U.S.C. § 1367 and 31 U.S.C. § 3732.

17. This Court has personal jurisdiction over Defendants, pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this District. In addition, the acts prohibited by 31 U.S.C. § 3729 occurred in this District. 31 U.S.C. § 3732(a).

18. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.

19. Relator's claims and this Amended Complaint are not based upon prior public

disclosures of allegations or transactions in a federal criminal, civil, or administrative hearing in which the Government is already a party, or in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation, or from the news media, as enumerated in 31 U.S.C. § 3730(c)(4)(A).[10]

20. To the extent that there has been a public disclosure unknown to the Relator, the Relator is the "original source" under 31 U.S.C. § 3730(e)(4)(B). The Relator has independent material knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing this *qui tam* action based on that information. *Id.*

IV. STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO DEFENDANTS' FALSE CLAIMS

A. BACKGROUND

21. Defendants serve as the institutional sponsors for a number of residency programs accredited by the Accreditation Council of Graduate Medical Education ("ACGME"). Relevant here, the ACGME lists MGH as the institutional sponsor for the HCORP, while Partners and MGH provide salary and benefits to HCORP residents. These residents are physicians with M.D. degrees who come to MGH and other Harvard-affiliated teaching hospitals to train an additional five years in orthopedics, their area of specialty.

22. At any given time, approximately 50 physicians train through HCORP. MGH's attending physicians, who hold Harvard Medical School ("HMS") faculty appointments, are charged with the training of HCORP residents and with supervising the care residents give MGH

[10] To the extent that conduct alleged in this amended complaint occurred prior to March 23, 2010, the prior versions of the False Claims Act may be applicable (i.e., 31 U.S.C. § 3730(e), as amended, October 27, 1986, and May 20, 2009).

patients.

23. MGH also trains fellows (individuals who have received their M.D.s and completed residencies) in orthopedic subspecialties including shoulder, spine, trauma and sports medicine.

24. As providers of Graduate Medical Education ("GME"), Defendants receive substantial payments from the United States government for resident physician[11] training and salaries though direct and indirect graduate medical education payments under Medicare Part A. In addition, MGH receives funding from other federal payers including the Departments of Defense and Veterans' Affairs, and some state Medicaid programs (collectively with payments under Medicare A "GME funds") to support their work in training residents.[12]

25. Fellows are often supported by GME funds as well.

26. The GME funds received from federal sources for graduate medical education are significant. In 2010, for example, Medicare contributed $9.5 billion to teaching hospitals in the United States to support the training of about 100,000 residents.[13] In addition, MGH receives funding to cover the cost of salaries and other overhead associated with resident training. MGH may bill Medicare Part B for the services (such as surgeries) rendered by teaching physicians on

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[11] A resident is a medical school graduate engaged in in-depth training in a medical specialty, which may last from 3-5 years depending upon the specialty. Residents are to be supervised by teaching physicians, also called "attending physicians," who approve their decision-making. According to the ACGME, a "resident" is "[a]ny physician in an accredited graduate medical education program, including interns, residents, and fellows." The ACGME defines a "fellow" as physician in a program of graduate medical education accredited by the ACGME who has completed the requirements for eligibility for first board certification in the specialty. The term 'subspecialty residents' is also applied to such physicians. Other uses of the term "fellow" require modifiers for precision and clarity, e.g., "research fellow." See AGME Glossary of Terms (Glossary of Terms, July 1, 2013); http://acgme.org/acgmewcb/Portals/O/PFAssets/Program Requirements/ab_ACGMEglossary.pdf.

[12] *Medicare Financing of Graduate Medical Education, Intractable Problems, Elusive Solutions*, Rich, Eugene C. et al., J. Gen. Inter. Med., 17; 283-292 (2002).

[13] *The Uncertain Future of Medicare and Graduate Medical Education*, Ingelhart, John K., New Eng. J. of Med., 365; 14, p. 1340 (2011).

its faculty incident to the instruction of residents, provided that all of Medicare and Medicaid rules are followed.

B. GOVERNMENT HEALTH CARE PROGRAMS

27. The federal and state governments, through Medicare and Medicaid, including MassHealth, are among the principal payers responsible for reimbursing Defendants for surgical services. Medicare is a federal government health program that primarily benefits the elderly and the disabled. It was created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by CMS, which is an agency of the Department of Health and Human Services ("HHS").

28. Medicare Part A covers the cost of inpatient hospital services and post-hospital skilled nursing facility care, and medical insurance. Medicare Part B covers the cost of the physician's services such as services to patients who are hospitalized, if the services are medically necessary and personally provided by the physician.

29. CMS establishes rules for the day-to-day administration of Medicare. CMS contracts with private companies to handle day-to-day administration of Medicare.

30. CMS, through contractors, maintains and distributes fee schedules for the payment of physician services. These schedules specify the amounts payable for defined types of medical services and procedures.

31. Hospitals generally are reimbursed under Medicare Part A on a reasonable cost basis for services provided to Medicare beneficiaries. Resident salaries are included among the costs for which hospitals are reimbursed under Part A, thus, services provided by residents typically cannot be billed under Medicare Part B.

32. As a Harvard-affiliated teaching hospital, engaged in the training of medical

students, residents and fellows ("trainees"), MGH is eligible to be reimbursed for the teaching activities of clinical faculty physicians (also referred to herein as "teaching physicians"). Teaching hospitals may also properly bill under Medicare Part B for medical services of attending physicians in limited circumstances where the attending physician is directly involved in providing patient services.

33. Congress created Medicaid at the same time it created Medicare in 1965 by adding Title XIX to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses primarily for low-income patients. Funding for Medicaid is shared between the federal and the state governments. The federal government also separately matches certain state expenses incurred in administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage. According to CMS, "[w]hen services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well."[14]

34. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for more than 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual health care plans, including Blue Cross and Blue Shield plans, Government Employees Hospital Association, and Rural Carrier Benefit Plan. FEHBP plans are managed by the U.S. Office of Personnel Management.

35. TRICARE is a federal program which provides civilian health benefits for military personnel, certain military retirees, and their families. TRICARE is administered by the

[14] *See* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/index.html?redirect=/certificationandcomplianc/02_ascs.asp (last visited April 25, 2017).

Department of Defense and funded by the federal government.

36. At all relevant times to the Amended Complaint, applicable TRICARE regulations relating to coverage of claims by providers and physicians have been substantially similar in all material respects to the applicable Medicare provisions described above. Medicare, Medicaid, and TRICARE, FEHBP and other similar federal and state medical insurance programs are referred to collectively herein as "government payers."

C. MEDICARE AND MEDICAID REIMBURSEMENT RULES AND CERTIFICATIONS

1. MEDICARE'S PAYMENT FOR SERVICES OF ATTENDING PHYSICIAN SURGEONS IN A TEACHING SETTING

37. To participate in the Medicare Program, hospitals enter "provider agreements" with the HHS Secretary. See 42 U.S.C. § 1395cc. The Medicare Program pays the hospital directly for covered inpatient and outpatient services provided to Medicare beneficiaries except for any deductible or coinsurance, which are collected from the beneficiaries. *Id.*

38. When submitting claims for reimbursement to the Medicare or Tricare, the provider is required on CMS Form 1500 to certify, *inter alia*, that: 1) the information on this form is true, accurate and complete; 2) sufficient information is provided to allow the government to make an informed eligibility and payment decision; 3) the claim complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment; and 4) the services on this form were medically necessary.[15] The form further requires the provider to certify that the services on the form were "personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE." *Id.*

[15] CMS Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf, last visited Apr. 25, 2017).

39. In a teaching setting like MGH, in order to receive payment under Part B for services performed by a physician, the service must meet one of the following criteria: (a) the services are personally furnished by a physician who is not a resident; or (b) the services are furnished by a resident in the presence of a fully-licensed, teaching physician. 42 C.F.R. § 415.170.

40. If a resident participates in a service furnished in a teaching setting, the service is eligible for a physician fee schedule payment "only if a teaching physician is present during the key portion of any service or procedure for which payment is sought." 42 C.F.R. § 415.172(a).

41. In the case of surgical, high-risk, or other complex procedures – such as all the procedures at issue in this Amended Complaint – the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. 42 C.F.R. § 415.172(a)(1).

42. If a teaching physician engages in two surgeries that overlap, the CMS Medicare Claims Processing Manual states, "[t]he critical or key portions *may not take place at the same time. When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure*." Emphasis Added, CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A.

43. Moreover "[d]uring non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, i.e., *he/she cannot be performing another procedure.*" Medicare Claims Processing Manual, 100.1.2-A Surgical Procedures at 153-155 (Jan. 4, 2010)[16] (emphasis added).

[16] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf (last viewed on May 16, 2017).

44. When a teaching physician is participating in second surgical procedure and "not present during non-critical or non-key portions of the [prior] procedure … *he/she must arrange for another qualified surgeon*[17] *to immediately assist* the resident in the other case should the need arise." CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A. The resident should not be conducting the surgery alone.

45. As summarized in the chart appended to the Senate Finance Committee Report, "Concurrent and Overlapping Surgeries: Additional Measures Warranted" (Dec. 6, 2016),[18] CMS defines concurrent surgeries as those where the critical or key parts of two surgeries are performed by the same teaching physician at the same time. The teaching physician is not allowed to bill for such surgeries. Overlapping surgeries are permitted as follows "[The] teaching physician must be present during the critical or key portions of both procedures. The teaching physician may become involved in a second procedure *when the key portions of the initial procedure have been completed.* If the teaching physician is not present during non-critical and non-key portions and is participating in another surgical procedure, she/he must arrange for another qualified surgeon to immediately assist in the other case should the need arise." *Id.* at 19. Otherwise CMS will not pay. The Senate Report notes that the American College of Surgeons (ACS) confirmed and clarified CMS's guidelines in its own clinical guidelines in April 2016. As the Report notes, the ACS guidelines reflect what is necessary for patient safety (pp.4-5).

46. The teaching physician may not submit for reimbursement under his/her name in

[17] CMS regulations require participating hospitals to "assure that personnel are licensed or met other applicable standards that are required by State or local laws." 42 C.F.R. §482.11(c) (Condition of participation; Compliance with Federal, State and local laws).

[18] See page 19 of the Appendix (hereafter "2016 Senate Finance Committee Report.") Available at www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf.

the case of three concurrent surgical procedures; here "the role of the teaching surgeon … in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is *not payable* under the physician fee schedule." CMS 2011 Claims Manual" at 100.1.2 (Surgical Procedures) at A. 2.

47. CMS policy expressly limits payment to services for which there is documentation demonstrating the appropriate level of services required by the patient. See Medicare Carriers Manual, Part 3 CMS Pub. 14-3 (Rev. 1780); 42 C.F.R. § 415.172 *et seq.*; 60 Fed. Reg. 63124-01, 1995 WL 723389 (F.R.).

48. When a teaching physician seeks reimbursement for a service involving a resident in the care of his/her patients "it must be identified as such on the claim" and is not payable unless it complies with the Claims Processing Manual. CMS 2011 Claims Manual at 100.1.8 (Physician Billing in the Teaching Setting) at B.

49. Moreover, the "teaching surgeon must personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures." 42 C.F.R. § 415.172.; CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A.2.

50. In sum, the teaching physician must appropriately document his/her involvement in the surgery when the resident performs elements of the surgery in the presence of, or jointly with, the teaching physician. The documentation must include sufficient information about the work performed during key portions of both procedures in the notes so that a "reviewer may clearly infer that the teaching physician was immediately available to return to either procedure in the event of complications." *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 823-24 (N. D.

Ill. 2013) (interpreting 2002 Medicare Claims Processing Manual).[19] Billing for a surgery that does not comply with the above Medicare/Medicaid rules is a false claim. *Id.*

51. Medicare and Medicaid providers are required to make restitution to the Medicare and Medicaid Programs when overpayments are identified unless the provider is without fault. See 42 U.S.C. § 1320a-7b(a)(3); see also 42 C.F.R. 405.350 *et seq.*; 42 C.F.R. § 489.20(b); OIG Compliance Guidance for Hospitals, 63 Fed. Reg. 8987, 8998 (Feb. 23, 1998).

2. MEDICAID'S PAYMENT FOR SERVICES OF ATTENDING PHYSICIAN SURGEONS IN A TEACHING SETTING

52. The Massachusetts Medicaid ("MassHealth") rules and regulations are similar to the federal rules, but the regulations, although consistent with the intent of their federal counterparts, more clearly define the necessary role of the teaching physician in any operative procedure submitted for reimbursement.

53. MassHealth Policy Manual, in the section entitled "Covered Services," states that it "will pay for medical services ... performed in a teaching setting" if certain enumerated requirements are met, including the following:

- In performance of surgery services the "teaching physician is responsible for the preoperative, intra-operative, and postoperative care of the [MassHealth] member;"
- "The teaching physician must be scrubbed and physically present during the key portion of the surgical procedure;"
- "During the intra-operative period in which the teaching physician is not physically present, he or she must remain immediately available to return to the procedure, if necessary. He or she must not be involved in another procedure from which he or she cannot return;" and
- "If the teaching physician leaves the operating room after the key portion(s) of the surgical procedure or during the closing of the surgical site to become involved in another

[19] 1996 Rules § 15016(C)(3)(a)(2) of the Medicare Claims Processing Manual (Transmittal 1780)(November 22, 2002). *See*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1780B3.pdf (last visited Apr. 25, 2017).

> surgical procedure, he or she *must arrange for another teaching physician* to be immediately available to intervene as needed. *The designee must be a physician (excluding a resident) who is not involved in or immediately available for any other surgical procedure*."

Emphasis Added. 130 CMR ¶ 450.275(D) and (D)(4).

54. MassHealth regulations define "teaching setting," "resident," and "teaching physician" as follows:

> (1) *Resident* — an individual who participates in an approved Graduate Medical Education (GME) program, including interns and fellows. A medical student is never considered a resident.
>
> (2) *Teaching Physician* — a physician (not a resident) who involves residents in the care of his or her patients. Where applicable and appropriate, the use of the phrase 'teaching physician' will be construed to include teaching podiatrists and teaching dentists.
>
> (3) *Teaching Setting* — a setting in which there is an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.

130 CMR ¶ 450.275(A)(1)-(3).

55. MassHealth will not reimburse for concurrent surgeries unless the teaching physician is present during the "key portions of both operations." 130 CMR ¶ 450.275(D)(4)(a). The "key portions must not occur simultaneously. When all of the key portions of the first procedure have been completed, the teaching physician may initiate his or her involvement in a second procedure." *Id.*

56. MassHealth regulations require the teaching physician to "personally document the key portions of both procedures in his or her notes *to demonstrate that he or she was immediately available to return to either procedure as needed.*" *Id.* (emphasis added). These documentation requirements, like the rules related to billing for surgeries provided in a teaching setting, are conditions of payment and, therefore, failure to comply renders the claim un-reimburseable. 130 CMR ¶ 450.275(D).

3. MEDICARE REIMBURSEMENT RULES PERTAINING TO REIMBURSMENT OF ANESTHESIA

57. Medicare reimburses anesthesia practitioners for the period of time during which they are "present with the patient." Medicare Claims Processing Manual at "50-Payment for Anesthesia Services" (Rev. 3583, 08-12-16). Specifically, the billing period or "anesthesia time" begins "when the anesthesia practitioner begins to prepare the patient for anesthesia services in the operating room or an equivalent area and ends when the anesthesia practitioner is no longer furnishing anesthesia to the patient, that is, when the patient may be placed safely under postoperative care." *Id.* Furthermore, anesthesia time is a "continuous" time block *and* the actual amount of time spent with the patient is "reported on the claim" for payment. *Id.* For computing payment, anesthesia time is divided into 15-minute increments and rounded up to one decimal place. *Id.*

58. Administering anesthesia to patients while they wait for extended periods for their surgeon to scrub in from another surgery – that is intentionally scheduled and conducted at the same time – is not reimbursable. This is because "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which … are not *reasonable and necessary* for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added).

59. It is not reasonable or necessary – and it is dangerous – to place patients under anesthesia without medical justification. MGH on its website quotes its own "world renowned anesthesiologist and computational scientist" Emery N. Brown, M.D., Ph.D., "[o]ur objective is to precisely control the brain circuits so that the anesthetic state exists *only for the time that it is needed,* is rapidly turned off and the patient recovers immediately with a clear head and is pain free." (emphasis added).

4. MEDICARE REIMBURSEMENT RULES PERTAINING TO INFORMED CONSENT

60. Ensuring that Medicare and Medicaid patients have given adequate informed consent, prior to medical procedures, is a condition of participation in the Medicare program. See generally, 42 C.F.R. § 482.13 (Condition of participation: Patient's rights). Obtaining proper informed consent is *also* a condition of payment. Specifically, the CMS State Operations Manual states that "[h]ospitals are required to be in compliance with the federal requirements set for the Medicare Conditions of Participation (COP) *in order to receive Medicare/Medicaid payment*." (Emphasis Added) CMS – State Operations Manual – Regulations and Interpretive Guidelines for Hospitals (Rev. 151; 11-20-15).

61. Among other requirements, CMS COPs include numerous informed consent rules designed to protect Medicare and Medicaid patients. For example, patients must have involvement, *inter alia*, in their own plan of care and be offered the ability to refuse treatment. 42 C.F.R. § 482.13(b)(1) & (2). Medicare and Medicaid patients also have the "right to receive care in a safe setting." 42 C.F.R. § 482.13(c)(2). A "properly executed" informed consent form must be included in each patient's chart prior to surgery. 42 C.F.R. § 482.51(b)(2)(Condition of participation: Surgical services); see also 42 C.F.R. § 482.24(c)(2)(B)(v) (Condition of participation: Medical record services).

62. CMS's adoption of interpretive guidelines for informed consent highlights the importance of compliance and the centrality of appropriate informed consent to participation in the payment under Medicare. 2007 CMS *Hospital Interpretive Guidelines for Informed Consent*,

extensively revised in 2007, state that a "well designed consent process" would, among other things, include:[20]

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;

○ *For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:*

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[20] April 13, 2007 CMS "Revisions to the Hospital Interpretive Guidelines for Informed Consent" at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter07-17.pdf (last visited Apr. 25, 2017).

- That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;

- That it will be decided at the time of the surgery which residents will participate and their manner of participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition; and

- *Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents.*

(Emphasis Added).

D. THE FALSE CLAIMS ACT AND THE MASSACHUSETTS FALSE CLAIMS LAW

63. The federal False Claims Act and the Massachusetts False Claims Law provide that any person who (1) knowingly presents or causes another to present a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of between $5,500 and $11,000[21] for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A) & (a)(1)(B); M.G.L. c.12, §§ 5B (1) & (2).

64. These statutes also both contain a "reverse-false-claims" provision, which hold liable persons or corporations who knowingly retain overpayments from the

[21] As adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410 section 5 (Oct. 5, 1990),104 Stat. 890.

government. 31 U.S.C. § 3729 (a)(1)(G); M.G.L. c.12, §§ 5B (8).

V. SPECIFIC ALLEGATIONS OF DEFENDANTS' FALSE CLAIMS

A. FALSE CLAIMS FOR CONCURRENT SURGERIES CONDUCTED WITHOUT ADDITIONAL COVERAGE BY QUALIFIED TEACHING PHYSICIANS

65. In or about 2010, MGH assigned Relator to provide in-patient anesthesia services to surgical patients in its Department of Orthopaedic Surgery.[22] In the course of providing anesthesia to patients undergoing surgery, Relator became aware of the practice within this Department of booking two or three surgeries to occur at the same time ("concurrent surgeries" also "double booking" and "triple booking") with the same attending surgeon listed as the lead on each surgery. The practice necessitates that those in training at MGH, residents and fellows, conduct some or all of the surgery outside of the presence of the teaching physician.

66. Over time, Relator learned that certain orthopedic surgeons regularly booked two surgeries concurrently in the morning and then two surgeries concurrently in the afternoon. In fact, she learned that it was not uncommon for a single orthopedic surgeon at MGH to schedule three surgeries concurrently, including two or more complicated or

[22] Among her duties as an attending physician at MGH and a member of the Harvard Medical School ("HMS") faculty, Dr. Wollman trained Harvard medical students, MGH/HMS residents, and fellows in anesthesia. From 1993 to 2010, Dr. Wollman primarily provided anesthesia services to patients undergoing cardiac, thoracic or out-patient surgery performed by MGH surgeons. In 2010, Dr. Wollman was selected, along with other anesthesiologists, to work on a dedicated floor providing in-patient anesthesia for surgical patients in the MGH Department of Orthopaedic Surgery. During her tenure working as an anesthesiologist alongside surgeons in this Department, Dr. Wollman gained first-hand knowledge of MGH's deliberate strategy and willful conspiracy to engage in and then cover up violations of billing rules and regulations established by Government payers, including Medicare and Medicaid, with regard to orthopedic surgeries performed at MGH. She reported such violations to MGH but was reprimanded, silenced, and marginalized for her efforts. Dr. Wollman decided to resign her employment at MGH in 2015 to take a position at another healthcare institution in the Boston area.

high risk procedures, such as total shoulder replacement, cervical, lumbar and spine surgeries and the surgical repair of non-emergent fractures.

67. The procedures did not merely overlap on their margins; they were instead scheduled at or about the same time, making it impossible for the teaching physician to assure that he could be physically present and ready to participate in the key or critical parts of each surgical procedure.

68. MGH's orthopedic operating schedules make clear that numerous surgeons are routinely performing concurrent surgeries in the morning and afternoon hours. Relator reviewed these schedules frequently when providing anesthesia to patients who were concurrently booked with the same surgeon and when she provided regional block services[23] for all patients undergoing surgery on days when she served on rotation as the attending anesthesiologist.

69. For example, on October 27, 2011, Relator observed that Surgeon A[24] scheduled a removal of a right shoulder prosthesis at 9:45 A.M. and a total shoulder joint replacement at 10:00 A.M. Each of these surgeries normally requires about 3 hours, and on this day, Relator observed that both patients were put under general anesthesia about the same time and Relator's patient (patient 1) – who was over 65 years old and, thus, Medicare eligible – was on medication the entire time to sustain his blood pressure.

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[23] On a rotating basis, Relator served as the "blocking attending," that is, as the member of the Anesthesia Department who administered the regional blocks for all the patients undergoing orthopedic surgery. When an anesthesiologist serves as the "block attending," she/he is required to review patient charts before administering the anesthetic block and in order to appropriately schedule the 10-12 patients under her care.

[24] Relator has substituted the names of the surgeons with an alias, such as Surgeon A, and will provide the names to Defendants by letter following service of this Amended Complaint. Relator has done so to protect the interests of patients.

Surgeon A did not even scrub for patient 1's surgery until an hour and a half *after* patient 1 was rendered unconscious, paralyzed, intubated and put on a ventilator.[25] During the time Surgeon A performed surgery on patient 1 – for about an hour and fifteen minutes – he was not immediately available for patient 2's surgery. Relator noticed that Surgeon A attested that he participated in the entire surgery for patient 1 even though it was false. Relator reported this to the compliance department at MGH. The attestation was later corrected but Surgeon A was never reprimanded to Relator's knowledge.

70. Likewise, on April 12, 2012, Surgeon A concurrently scheduled the right shoulder scope acromionplasty of a woman to whom Relator provided anesthesia (Patient 1) and a shoulder replacement of another woman (Patient 2) in another room. Patient 2's procedure took approximately four hours and fifteen minutes to perform and Surgeon A was seeing other patients. Accordingly, Patient 1's surgery was essentially performed by a fellow. Relator noted that Surgeon A scrubbed in for just nine minutes of Patient 1's surgery. Patient 1 was asleep for an excessive time waiting for Surgeon A to arrive. Both of the patients involved here were over 65 and, thus, Medicare eligible.

71. Weeks later, on May 3, 2012, Surgeon A had concurrent surgeries running while he was seeing patients in his office in another building on MGH's campus. To no avail, Relator complained to high level officials about his conduct.

72. On January 15, 2015, Surgeon C had fracture repair surgeries on two separate patients that both began around noon and lasted for three hours. Both patients were in their seventies and most likely Medicare patients. In short, it was impossible for Surgeon C to be immediately available for both surgeries and, here, the likelihood of

[25] This is what general anesthesia consists of.

complications for elderly patients is increased.

73. Concurrent scheduling was a routine occurrence during Relator's tenure in MGH's Department of Orthopaedics and continued, to her knowledge, at least until 2015.

74. MGH's operating room schedules make clear that MGH orthopedic surgeons often perform multiple major surgeries simultaneously. Relator observed that MGH's orthopedic operating schedule for numerous dates in 2011 through 2013 demonstrates at least the following instances of surgeons covering multiple surgeries at once.

Date	Surgeon	Schedule
July 7, 2011	Surgeon C	9:53 a.m., Room 21, Right Total Knee Arthroplasty/Replacement; Duration: 3:07 hours 10:25 a.m., Room 22, Right Femur Trochanteric nail insertion; Duration: 2:32 hours.
May 19, 2011	Surgeon A	9:45 a.m., Room 20; Left Total Shoulder Joint Replacement, Primary, Uncomplicated; Duration 4:15 hours 9:45 a.m.; Room Unknown; Left Shoulder Anatomic Inverse Arthroplasty; Duration 4:45 hours 2:00 p.m., Room 20; Left Total Shoulder Joint Replacement; Duration 4:00 hours. 2:30 p.m., Room 23, Left Proximal Humerus Fracture Orif; Duration 4:30 hours.
October 3, 2011	Surgeon D	8:08 a.m.; Room 72, Lumbar Laminectomy Less than 3 Levels - Laminectomy L3-4; Duration 2:52 hours; 8:15 a.m., Room 64; Cervical Posterior Decompression and Fusion - Cervical Posterior Spinal Fusion and Decomp C2-C-5 (Latex Allergy); Duration 4:51.

		11:57 a.m., Room 72, Removal Lumbar Spine Hardware - 1) Post Hardware Removal 2) ANT L5 CORP. 3) PSF TIO-ILIUM; Duration: 8:03hours. 2:08 p.m., Room 64; Coccygectomy; Duration 1:35 hours
October 27, 2011	Surgeon A	9:49 a.m.; Room 67; Right Shoulder Reverse Prosthesis Hardware Removal - Right Shoulder Open Removal of Prosthesis, Prostalac Placement; Duration 6:34 hours. 9:50 a.m.; Room 66; Right Total Shoulder Joint Replacement, Primary, Uncomplicated; Duration 3:44 hours. 2:42 p.m.; Room 66; Left Total Shoulder Joint Replacement, Primary, Uncomplicated; Duration 4:14 hours.
October 31, 2011	Surgeon B	8:04 a.m.; Room 69; Left Elbow Fracture Orif- Hardware Removal Left Elbow; Duration 3:18 hours 8:35 a.m.; Room 70; Incision & Drainage (I&D) -- Right Leg/Wound VAC Dressing Change -- Duration 1:10 hours
November 3, 2011	Surgeon A	9:47 a.m.; Room 66, Right Total Shoulder Joint Replacement, Primary, Uncomplicated; Duration 4:48 hours 9:57 a.m.; Room 67, Left Total Shoulder Joint Replacement, Primary, Uncomplicated; Duration: 3:46 hours. 2:31 p.m.; Room 67, Right Should Hardware Removal - Right Shoulder I&D, Hardware Removal, Antibiotic Spacer Placement; Duration 3:32 hours. 3:25 p.m.; Room 66; Left Pectorals Major Transfer: Duration: 3:03 hours
November 7, 2011	Surgeon A	7:35 a.m.; Room 69; Right Shoulder Excisional Debridement; Duration 2:21 hours 8:00 a.m.; Room 67; Left Pectoralis Major Transfer; duration 3:52 hours. 10:41 a.m.; Room 69; Right Total Shoulder Joint Replacement, Primary, Uncomplicated Duration 4:44 hours

		12:15 p.m.; Room 67; Right Shoulder Anatomic Inverse Arthroplasty; Duration 4:45 hours
November 8, 2011	Surgeon E	7:40 a.m.; Room 70; Left Distal Radius Fracture Closed Reduction vs. Orif; Duration 1:52 hours. 8:47 a.m., Room 69, Left Revision of Total Hip Arthroplasty All Components Possible Autograft or Allograft (27134); Duration 5:32 hours. 11:55 a.m.; Room 70; Right Total Hip Arthroplasty Revision; duration 4:34 hours. 3:20 p.m.; Room 69; Right Ankle Fracture Or if; Duration 2:36 hours
November 22, 2011	Surgeon E	7:50 a.m.; Room 69; Right Hamstring Repair- Right Proximal Hamstring Repair; Duration: 2:05 hours. 8:00 a.m.; Room 70; Left Total Hip Arthroplasty Revision; Duration: 4:39 hours.
March 5, 2012	Surgeon D	7:43 a.m.; Room 64; Lumbar Posterior Decompression with Fusion FSF& Decompression L2-Sl; Duration 8:53 hours. 7:40 a.m.; Room 72; Lumbar Posterior Decompression with Fusion FSF& Decompression L4-S1; Duration 4:56 hours. 1:25 p.m.; Room 72; Lumbar Posterior Decompression with Fusion FSF& Decompression L4-S1; Duration: 4:23 hours.
March 5, 2012	Surgeon B	3:14 p.m.; Room 70; Left Open Reduction Internal Fixation of Intertrochanteric/Petrochanteric/Subtrochanteric Femoral Fracture with Intramedullary Implant, Possible Interlocking Screws and/or Cerclage; Duration 1:51 hours. 3:36 p.m.; Room 69, Left Open Reduction Internal Fixation of Trochanteric Fractures with Intramedullary Implant Possible Plate/Screw or Cerclage (27245) - Short TFN; Duration: 1:55 hours.
March 27, 2012	Surgeon E	11:48 a.m.; Room 70; Right Open Reduction Internal Fixation of Trochanteric Fractures with Intramedullary Implant Possible Plate/Screw or Cerclage (27245); Duration 2:45 hours.

		12:04 p.m.; Room 69; Right Open Reduction Internal Fixation of Femoral Supracondylar/Transcondylar Fracture without Intercondylar Extension with Possible External Fixation (27511); Duration: 3:27 hours. 3:15 p.m.; Room 70; Left Hemiarthroplasty Hip (27125); Duration 2:36 hours. 4:20 p.m.; Room 69; Left Open Internal Fixation of Tibial Shaft Fracture with Intramedullary Implant Possible Interlocking Screws or Cerclage (27759); Duration 1:46 hours.
April 12, 2012	Surgeon D	9:35 a.m., Room 73; Lumbar Posterior Decompression with Fusion - PSF & Decompression; Duration: 4:10 9:40 a.m.; Room 72; Lumbar Anterior Posterior Fusion-ASF L5-S1 PSF L5-S1; Duration 5:57 hours.
May 29, 2012	Surgeon E	1:21 p.m.; Room 70; Left Femur Fracture Orif; Duration 4:13 hours. 2:00 p.m.; Room 65; Left Leg Hardware Removal - Screw Removal at Tib Fib; Duration: 51 minutes.
August 6, 2012	Surgeon D	7:42 a.m.; Room 64; Lumbar Anterior Fusion - ASF L5-Sl Removal of Lumbar Hardware L2- L5; Duration: 7:20 hours. 8:00 a.m.; Room 72; Cervical Anterior Corpectomy - Cervical Anterior Corpectomy C3-C6 Cervical PSF & Decompression C2-C6; Duration 11:37 hours.
March 12, 2013	Surgeon E	7:33 a.m.; Room 70, Right Open Reduction Internal Fixation of Intertrochanteric/Pertrochanteric/Subtrochanteric Femoral Facture with Intramedullary Implant, Possible interlocking Screws and/or Cerclage; Duration 1:51 hours. 7:45 a.m.; Room 63; Left Ankle Fracture Orif (27816); Duration 1:42 hours.

75. These are but a few examples of the concurrent surgery practice that continued at least until 2015. In each of the examples above, at least one or more of the patients involved in concurrent surgeries was 65 years of age or older, meaning Medicare eligible patients were involved in the submissions of claims for these specific procedures.

76. MGH admits on its website that in 2014 approximately 5,500 surgeries "had some case overlap" but claims that only about 3% of the total surgeries (or about 1,110 surgeries) involved overlap of the "actual surgical procedures." MGH Frequently Asked Questions about Concurrent/Overlapping Surgeries ("MGH FAQs").[26] According to MGH, "procedural overlap [in concurrent surgeries] … usually involves the resident or fellow making the incision or closing the incision while the attending [teaching] surgeon is caring for a patient in another operating room." *Id.* The schedules above show that concurrent surgeries were not staggered in such a way that minimal "procedural overlap" was possible. In some cases, surgeries began and ended at approximately the same time; while some were of such long duration that it was not possible for the teaching physician to be present for significant time periods. MGH has publicly championed its concurrent surgery practice even though it provides no benefit to the patient receiving surgery or to the taxpayers who fund Medicare and Medicaid.

77. For those 65 and older, the risks of surgery are most acute and are only compounded by the hospital's failure to follow Medicare and Medicaid rules, including those requiring additional coverage of concurrent surgeries by another qualified teaching physician.

78. Indeed Relator learned problems frequently arose when patients needed prompt attention from a surgeon who was otherwise engaged. Because MGH violated (and continues to violate) Medicare and Medicaid rules requiring another qualified teaching physician to be on stand-by to assist residents and fellows in surgeries where the teaching physician had moved on to another surgery,[27] residents and fellows were left without supervision in concurrent surgeries performed in the Department of Orthopaedics.

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[26] MGH FAQs available at http://www.massgeneral.org/news/assets/pdf/surgery-faq.pdf (last visited Apr. 25, 2017).

[27] CMS 2011 Claims Manual at 100.1.2 (Surgical Procedures) A; 130 CMR ¶ 450.275(D)(4).

79. In no concurrent orthopedic surgery in which Realtor was required to participate during her tenure at MGH, was another qualified and available teaching physician designated or utilized. Likewise, when reviewing medical charts and surgical records while at MGH in the course of her duties, Relator has seen no evidence of compliance with the Medicare and Medicaid rules mandating such practice. Instead, in emergency situations the hospital scrambled to find someone qualified to take over from a resident or fellow who had been abandoned by the teaching surgeon.

80. Defendants' violations have caused harm. Relator is aware of some emergency situations that could have been avoided if the rules were followed but it was not profitable for MGH or the teaching physicians themselves to cover for one another.

81. For example, Relator learned on one occasion that a shoulder fellow – left in an operating room without supervision while the teaching physician was operating on another patient in a second concurrently scheduled surgery – severed the axillary artery of the patient, requiring transfusions and emergency repair by a vascular surgeon.

82. Relator is also aware that on the Friday after Thanksgiving 2013, a trauma surgeon scheduled three concurrent surgeries. One of the three patients was a young woman who was having a simple removal of hardware in her foot from a previous surgery. During her surgery, she experienced cardiac arrest requiring cardiopulmonary resuscitation and transfer to an intensive care unit. Meanwhile, the other two patients in the other rooms were under anesthesia with no attending surgeon.[28]

[28] Also in or about 2015, a vascular surgeon engaged in concurrent booking resulted in patient harm. When a resident filed a safety report, she was chastised for so doing. The practice has occurred recently in the Department of Neurosurgery as well as in other MGH Departments over time.

83. The previous year, in 2012, MGH's Department of Orthopaedics issued new rules regarding concurrent surgery practices, but failed to adequately address the Medicare and Medicaid rules requiring additional coverage of concurrent surgeries.

84. For example, MGH wrongly decided that a fellow – already engaged in the surgery with the teaching physician before he left for another surgery – could serve as a back-up even though fellows are not yet qualified or credentialed by MGH to perform the surgeries they are learning *and* do not meet the MassHealth conditions of payment for at least two reasons. Specifically, only a "teaching physician" may serve a back-up surgeon. 130 CMR ¶ 450.275(A)(2). The regulations define a teaching physician as "a physician (not a resident) who involves residents in the care of his or her patients." *Id.* Under the rules, fellows are considered residents. 130 CMR ¶ 450.275(A)(2). Moreover fellows, already involved in the surgery, do not satisfy the temporal requirement of the rule that the back-up surgeon not be "*involved in or immediately available for any other surgical procedure*." 130 CMR ¶ 450.275(D)(4)

85. Likewise, the federal regulations specify that a teaching physician will not be paid if he is not present or immediately available to return to the surgery. 42 C.F.R. 415.172(a)(1). Once the surgeon has left the first surgery and is engaged in another surgery, he cannot return to the first surgery and receive payment. Specifically, "[d]uring non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, i.e., *he/she cannot be performing another procedure.*" Medicare Claims Processing Manual, 100.1.2-A Surgical Procedures at 153-155 (Jan. 4, 2010) (emphasis added). Therefore, virtually every claim submitted by MGH for concurrent surgeries to Medicare and MassHealth is not payable and is a false claim.

B. UNREASONABLE AND UNNECESSARY ANESTHESIA CLAIMS

86. Because Relator was routinely assigned to work with orthopedic surgeons who scheduled concurrent surgeries, she witnessed first-hand compromised clinical care resulting from concurrent booking.

87. Even where there were no major complications, otherwise healthy patients were made unconscious, paralyzed, and intubated for an unnecessarily prolonged period of time awaiting surgery,[29] needlessly risking their health and increasing costs to government payers, which reimburse anesthesiologists by the amount of time spent with patients under anesthesia. Often residents or fellows completed non-critical parts of the surgery and simply waited for the teaching surgeon to continue with the critical parts.

88. For example, on April 22, 2013, Relator reported an incident where a patient had a serious bronchospasm (a sudden constriction of air ways in the lungs) during ankle surgery, occurring at the end of the day. Relator was the physician in charge of the patient's anesthesia and noted that the surgery took over an hour longer than projected because the teaching surgeon, Surgeon B, never appeared in the room. A fellow performed all of the procedures even though they were scheduled to be performed by Surgeon B. Relator's email to the OR Director asked, "isn't he [Surgeon B] obligated to be there?"

89. Relator's supervisors, Jeanine Weiner-Kronish, M.D., the Chief of Anesthesia and Critical Care, and James Rathmell, M.D., the Vice Chair, Department of Anesthesia and Critical

[29]MGH's informed consent form, dated October 2014, acknowledges and warns patients about the unique risks associated with the use of anesthesia: If procedural sedation will be used during this procedure to control my pain, I understand that this method of pain control has risks. These risks include difficulty breathing that may require breathing support and decreased blood pressure. The most common side effects are nausea and vomiting. In rare cases, there can be allergic reactions or cardiac arrest (stopping of the heart). Lastly, I may have pain, even after using these medications.

Care, did not follow up on Dr. Wollman's concerns, except to threaten her by suggesting that she had violated patient privacy and could face legal action. When she raised concerns to Dr. Peter Dunn, MGH's Director of the Operating Rooms ("OR Director"), he too questioned Dr. Wollman's motivation in reviewing charts when serving as a block attending, raising the possibility that the hospital could accuse her of violating HIPPA and take disciplinary action against her.[30]

90. The charge was specious. When an anesthesiologist serves as the "block attending," she/he is required to review patient charts before administering the anesthetic block and in order to appropriately schedule the 10-12 patients under her care.

91. To be sure, while Dr. Wollman discharged her duties, she grew concerned about the unnecessary prolonging of the anesthesia administered to a patient while waiting for a surgeon who had booked more than one surgery concurrently. Dr. Wollman's expression of concern certainly did not implicate HIPPA or constitute a failure to comply with its requirements.

92. The practice of billing for unreasonable and unnecessary anesthesia was not a remote occurrence in MGH's Department of Orthopaedics. Rather, it was commonplace and a direct outgrowth of the concurrent surgery practice which, to succeed, required patients to be put under general anesthesia waiting for their surgeon to arrive.[31] For this reason, virtually every claim by MGH for concurrent surgeries contains inflated charges for anesthesia services and is a false claim.

C. FAILURE TO OBTAIN VALID INFORMED CONSENT

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[30] See generally Health Insurance Portability and Accountability Act of 1996 (HIPPA) privacy regulations, 45 C.F.R. Part 160 and Subparts A and E of Part 164.

[31] The situation is analogous to the following: Consider an airport with multiple gates and the gate agents want to leave at 3 p.m. Hence the gate agents board all planes targeted for take-off between 2:30 p.m. and 6:00 p.m. at 2 p.m. – requiring the passengers sit on the planes parked the tarmac waiting for take-off. The only distinction is that the air plane passengers are not under anesthesia and are aware enough to complain.

93. Over the years, Defendants have utilized various informed consent forms – which are to be reviewed and signed by patients before surgery – but none has informed patients that their surgeon would not be present during the entire surgery because the surgeon had intended to perform another surgery at the same time.

94. Specifically, a consent form utilized by MGH that is dated July 24, 2001 only notes that MGH "is an academic medical center and that residents, fellows and students in medical and allied disciplines may participate in this procedure."

95. By May 2013, after Relator and others had repeatedly raised concerns about the failure to inform patients of the routine practice of concurrent surgery, MGH's consent form had evolved somewhat to add that "My doctor will be there for the important parts of my procedure/surgery. My doctor will determine what other providers need to participate in my procedure/surgery and care," but there is still no mention that the surgeon will be out of the room working in another surgery.

96. In response to ongoing concerns, yet another consent form was created: this one included an exhaustive list of all physicians who conceivably could be involved in a patient's surgery, including residents, and including physicians who might not even be present at the Hospital on the date of the procedure. This kitchen sink approach to a consent form contained the list of physicians but is not effective notice to patients, especially when presented to them at a time when they are too ill or too worried about their impending surgeries to realize that they are consenting to a revolving door approach to the surgery they reasonably believe will be done by the attending physician who scheduled it and had examined them.

97. The current consent form, dated October 2014, is available on MGH's website. It also fails to mention that the surgeon may be working in two surgeries at the same time. It states:

> I understand that Massachusetts General Hospital (MGH) is a teaching hospital. This means that resident doctors, doctors in a medical fellowship (fellows) and students in medical, nursing and related health care professions receive training here, and may take part in my procedure/surgery. A team of medical professionals will work together to perform my procedure/surgery. My doctor or an attending designee will be present for all the critical parts of the procedure/surgery, although other medical professionals may perform some aspects of the procedure as my doctor or the attending designee deems appropriate.

98. MGH also has no official policy requiring anyone at MGH to disclose concurrent surgery to patients who are affected by the practice. While a 2012 MGH Policy: Criteria for Concurrent Staffing of Two Operating Rooms ("2012 Policy") suggests that various elements of the surgery be discussed with patients, including that the attending (teaching) surgeon "may not be present during non-critical portions of the case," and "may not perform or be present in the room for the entire case…" these discussions were not mandatory, not required to be documented and, in fact, almost never occurred. The 2012 Policy notes discussions about the surgeon's whereabouts during surgery are left to the discretion of the attending physician "to the extent [he] felt appropriate." Relator has first-hand knowledge that most patients were never told and did not otherwise know that their surgeon was scheduled to perform two or more surgeries at the same time. To the contrary: patients routinely sought assurance from Dr. Wollman that the attending physician with whom they had scheduled the surgery would be present and involved in the case.

99. Instead of meeting the Hospital's obligation of disclosure and informed consent, MGH actively sought to conceal its concurrent surgery practice from patients. For example, when Relator began her tenure in MGH's Department of Orthopaedics, nurses indicated that it was the Department's practice, not to put patients in the same room (or in the same room without a partition), in pre-operative phase, if the patients were going to be operated on at the same time by

the same surgeon because the patients might become upset or not agree to surgery if they knew the true facts.

100. In sum, the consent forms and MGH's policies and practices fail to meet criteria set out in the Medicare regulations, guidance documents, or state law and, therefore, surgeries billed by MGH for all concurrent surgeries are false claims.

101. Specifically, as the 2016 Senate Finance Committee Report points out, at page 10, CMS's COPs and corresponding interpretive guidelines, among other things:

> require hospitals to take certain steps to ensure that patients consent to planned surgeries. For example, this guidance states that a well-designed informed consent policy should include a discussion of a surgeon's possible absence during part of the patient's surgery, during which residents will perform surgical tasks, and that the informed consent policy should assure the patient's right to refuse treatment.

102. Submitting claims for concurrent surgeries where valid informed consent has not been obtained, much less documented in the patient's file, is material. Defendant has failed to provide full and proper informed consent with regard to the practices alleged herein because doing so would have a natural tendency to influence or be capable of influencing a patient's decision to consent to surgery under Defendants' practices. Because a patient is the initial gatekeeper for the payment by any government third party payers, the matter of informed consent is material because, *inter alia*, it has a natural tendency to influence, or be capable of influencing, the payment or receipt of government money.

103. Along the same lines, failure to obtain informed consent violates long-standing rules of ethics. According to the American Medical Association ("AMA"), "[a] surgeon who allows a substitute to operate on his or her patient without the patient's knowledge or consent is deceitful. The patient is entitled to choose his or her own doctor and should be permitted to

acquiesce or refuse the substitution." (Emphasis added). See AMA Council on Ethical and Judicial Affairs Opinion E-8.16 "Substitution of Surgeon without Patient's Knowledge or Consent." The Ethics Opinion goes on to state:

> Under the normal and customary arrangement with patients ... the operating surgeon is obligated to perform the operation but may be assisted by residents or other surgeons. With consent of the patient, it is not unethical for the operating surgeon to delegate the performance of certain aspects of the operation to the assistant provided this is done under the surgeon's participatory supervision, i.e., the surgeon must scrub. If a resident or other physician is to perform the operation under non-participatory supervision, it is necessary to make a full disclosure of this fact to the patient, and this should be evidenced by an appropriate statement in the consent. Under these circumstances, it is the resident or other physician who becomes the operating surgeon.

104. Likewise, Dr. Mininder S. Kocher in an article entitled *Ghost Surgery: The Ethical and Legal Implications of Who Does the Operation*, J Bone Joint Surg. Am. 84: 148-150 (2002), concluded that "[t]he substitution of an authorized surgeon by an unauthorized surgeon or the allowance of unauthorized surgical trainees to operate without adequate supervision constitutes 'ghost surgery.' These practices are legally and ethically iniquitous. Ghost surgery flies in the face of case law and violates an individual's right to control his or her own body and violates that person's right to information needed to make an informed decision."

105. MGH submitted false claims to the government for *all* Medicare/Medicaid patients receiving surgery in tandem or concurrently with one or more other patients because the hospital did not obtain valid informed consent from these patients.

D. FALSE AND INADEQUATE RECORD KEEPING

106. In the course of Relator's duties, she was privy to the surgical records generated by physicians performing concurrent surgeries. She noted that these records routinely failed to provide an accurate accounting of the teaching surgeon's involvement in the case, including the

nature of the procedures deemed to be "key and critical," the time in which he entered and exited the surgery room, whether he was able to return to the surgery if necessary, and/or whether another surgery was conducted at the same time.

107. Except in rare cases where the teaching surgeon was present for the entire procedure, none of the records kept by teaching physicians at MGH would have allowed a regulator to clearly infer that the teaching physician was immediately available to return to either procedure in the event of complications.

108. Also as discussed above, none of the records contained the name of a back-up teaching physician who was in fact available and qualified to take over if necessary. Instead, where fellows were involved they were designated, in violation of Medicare and Medicaid rules, as the back-up. Where residents were left alone, the records were silent. Failure to document appropriately work on concurrent surgeries is a condition of payment. 42 C.F.R. § 415.172(b) and 130 CMR 450.275 (D)(Covered Services). MGH submitted false claims to the government for all concurrent surgeries where the surgeon's records do comply with regulations.

E. MGH WAS WELL-AWARE OF MEDICARE AND MEDICAID VIOLATIONS AND RESULTING FALSE CLAIMS LIABILITY

109. When Dr. Wollman asked colleagues about the practice, she learned that prior efforts to address the problem had been ignored. When Neelakatan Sunder, M.D., who held a post of administrative leadership within the Department of Anesthesia, raised concerns, he was removed from that post. Moreover, when Dennis Burke, M.D. a renowned orthopedic surgeon at MGH, similarly tried to address the issue, he was rebuffed. Dr. Wollman added her voice, asking questions about the practice and its impact within her own Department, she was ignored at first and later threatened by her managers, as noted above, for delving into purportedly confidential patient matters.

110. In the spring of 2012, Relator felt obliged to raise her concerns to more senior leadership.

111. In May of 2012, focusing in on the conduct of a particular surgeon, Surgeon "A" Relator communicated by email to several high ranking administrators at the Defendant institutions, including David Torchiana, M.D., former Chairman and Chief Executive Officer of the MGPO (who recently left that position to become the President and Chief Executive Officer of Partners); Peter Slavin, M.D., President and Chief Executive Officer of MGH; Keith Lillemoe, M.D., MGH's Chief of Surgery; and Ann Prestipino, M.D., MGH Senior Vice President for Surgical Anesthesia Services and Clinical Business Development. Then Chief of Orthopaedics, Harry Rubash, M.D., was also made aware of her complaint.

112. Relator reported that she was in the process of preparing Surgeon A's patient for surgery. The patient asked to see Surgeon A prior to the procedure and to being given anesthesia. Relator sought out Surgeon A and learned that another patient had already been sedated in another operating room, also awaiting surgery by the same Surgeon A. While both patients awaited surgery (one already under anesthesia), Surgeon A was in another building on MGH's campus seeing yet other patients. In reporting the incident, Relator wrote "I am aware of at least one and possibly several cases where this same surgeon [Surgeon A] never scrubbed into the case; in one particular case, the patient was the wife of a surgeon who came from the west coast specifically for ... [his] surgical abilities." In response to Relator's email, Dr. Torchiana admitted that "[a]ttending surgeons, including .... [Surgeon A] are obligated to be present for the critical parts of their cases" and – seeking to assuage Relator – noted that MGH had begun an internal investigation of concurrent booking to address concerns voiced by numerous MGH physicians.

113. Relator hoped that this process would address the problem quickly, as she believed

"this issue of surgeon availability and presence in the OR [operating room] is not something that can wait for a committee to resolve or can be ignored. Patients deserve honesty and the surgical and anesthesia team should not be asked to participate in the deception that the surgeon is present for the 'critical parts' of the case."

114. The "deception" to which Relator referred was MGH's role in concealing the identity of the physicians performing the surgery – by failing to inform patients undergoing surgery that their attending physician would not necessarily be in the room during most of the procedure – and by too often falsifying and/or failing to adequately notate the medical records in conformance with Medicare and Medicaid rules. Had MGH followed these rules, the medical records would have revealed to the patient, at the very least, that his/her physician was absent.

115. Dr. Wollman learned that the investigation into the practices about which she had expressed concern concluded in the spring of 2012; yet the results were not disclosed; and little changed. While triple bookings were officially banned by a new written policy,[32] MGH did nothing to ensure that teaching surgeons were present for key and critical parts of their cases, that they were immediately available to residents needing assistance, as is required by the Medicare rules, or that the surgical records accurately reflected who participated in the surgical procedure.

116. In fact, Dr. Wollman was obliged to report a triple booking by Surgeon A on June 28, 2012 to MGH supervisors. She wrote, "I thought that a surgeon could not be in three rooms under any circumstances; I am not sure how this was able to be booked this way ... and [I] continue

[32] "MGH Policy: Criteria for Concurrent Staffing of Two Operating Rooms," was initially announced to physicians in or around June 2012 and was purportedly designed to address the concerns about concurrent booking, but the policy had no such effect. (Available at: https://assets.documentcloud.org/documents/2484257/mgh-draft-policy.pdf (last visited Apr. 25, 2017)).

to not be comfortable being put in this position."

117. Rather than disciplining Surgeon A or enforcing supervision rules hospital-wide, MGH informed Relator that she would no longer be permitted to work on cases with Surgeon A. When Relator questioned her supervisor, Robert Peloquin, M.D., MGH's Director of Orthopaedic Anesthesia, he informed her that because of the "history of poor communications" between Relator and Surgeon A, she was excluded from providing anesthesia to his patients. Yet, the only "poor communication" between the two members of the Medical Staff occurred when Surgeon A screamed at Relator for having him paged to meet his patient before surgery. Relator's exclusion was merely pretext for keeping concurrent surgeries from further scrutiny.

118. Relator addressed her concern to Dr. Peter Dunn about MGH's decision to exclude her from working with Surgeon A. She asked "what, if anything, has been done to date, to address ... [Surgeon A's] behavior and responses in the OR ... [?]" Dr. Dunn never responded, nor did MGH. By excluding Relator from working with Surgeon A, Defendants assured that no other complaints by Relator – at least with regard to Surgeon A – would surface.

119. Relator's concerns were mirrored by other well-respected health care professionals including Dennis Burke, M.D.; an orthopedic surgeon on MGH's Medical Staff and a member of the HMS faculty who specializes in arthroplasty (total joint replacement) who has been honored by the institution itself for his commitment to excellence in patient care.

120. Over time, Dr. Burke had made sure senior leadership within the Department of Orthopaedic Surgery and within MGH, more generally, were aware of the practice of concurrent surgery, its implications for patient care, and the integrity of MGH's medical records and billings.

121. On February 2, 2011, Dr. Burke reported his concerns to the MGH leadership, writing Dr. Torchiana about a 91-year-old patient who bled to death shortly after having an elective

surgical procedure. The attending orthopedic surgeon in charge was listed as the attending in another operating room at the very same time. He also reported to Dr. Torchiana his concern about a patient who had required emergency surgery, following an unsuccessful surgery by another orthopedic surgeon at the hospital. Dr. Burke reported that the attending physician in charge of the patient's first surgical procedure had also been listed as the attending in charge of patients in three operating rooms concurrently. According to the anesthesiologist involved in the first procedure, the attending surgeon was not immediately present for the critical stage of the surgery; nor did he respond to repeated pages. It was only upon the insistence of the treating anesthesiologist that the attending physician in charge of the patient's care appeared in the room. When a resident involved in the procedure suggested that materials to be used in the procedure needed to be mixed again, given the time lapse, the surgeon rebuffed the concern and proceeded.

122. At the time, Dr. Burke reported these events to Dr. Torchiana, he did so because he had not received any indication from his own Department of Orthopaedics that the problems posed by concurrent surgeries were being considered.

123. In addition to detailing certain specific cases where there was a significant risk that patient harm resulted from the practice of concurrent surgery, on February of 2011, Dr. Burke reported that, based on what he had learned, there was also a troubling pattern involving the "apparent falsification of records by nursing and house staff that made it appear that a surgeon scheduled simultaneously in two rooms performed both operations."

124. Dr. Burke noted that he had learned that the records were not remotely accurate and that there existed cases where the attending physician listed as the surgeon in charge of the procedure "apparently never entered the second theater, no less performed that operation."

125. Dr. Burke specifically warned Dr. Torchiana in his February 2011 letter "not [to]

rely on medical records for [a] compliance measure," as it was a "'running joke among some of us that the phrase - 'I was present for the critical part of the operation and Dr So and So was immediately available' are cynical code words from the inattentive surgeon absent from his post.'" Dr. Burke also argued that lying on patient records about the presence of surgeons "is unacceptable from an ethical and moral perspective and bad behavior, when it is tolerated and encouraged becomes normative and pervasive."

126. Like Relator, Dr. Burke also repeatedly raised the lack of informed consent inherent in concurrent bookings, telling MGH administrators that patients would be shocked if they knew that concurrent surgeries primarily or exclusively conducted by residents could occur at MGH. At one meeting where Dr. Burke questioned the problems of informed consent, an MGH official scoffed and told him not to worry because consent forms "weren't worth the paper they were printed on."

127. Disregard of the concerns that Relator raised by MGH leadership and its physicians group, the MGPO, is not surprising: Routine concurrent surgery was part of the plan for increasing surgical volume when Dr. Rubash came on as the Chief of Orthopaedics at MGH in 2000, bringing along colleagues of his from the University of Pittsburgh's Medical School where the business model of concurrently booking surgeries was mainstreamed for the purpose of increasing revenues to the university and individual physicians. Dr. Rubash, who remained until the Summer of 2016 the Chief of Orthopaedic Surgery at MGH and who remains still an endowed chaired professor at Harvard Medical School, implemented a similar program at MGH by creating strong economic incentives for attending MGH surgeons to increase their own compensation based, in part, on the number of surgical procedures performed under their names, for which the Hospital received reimbursement.

128. Before Dr. Rubash's plan, surgeons were paid a salary, which was not specifically and directly tied to billing or grants. That changed under Dr. Rubash. The Harvard Business School chronicled the financial success of Dr. Rubash's physician incentive plan in a case study published on October 31, 2005, entitled "Performance Pay for MGOA Physicians (B)." The case study chronicles a significant rise in hospital revenues tied to the shift in compensation through volume incentives for orthopedic surgeons. The case study demonstrates the sharp increase in monetary remuneration that certain orthopedic surgeons enjoyed as a result of their surgical volume. On information and belief, in large measure, this increase was a result of concurrent surgeries. It appears from the study that certain orthopedic surgeons currently book surgeries to increase their own compensation while not in fact increasing their personal workload, as they leave residents to handle procedures under their name. For example, one orthopedic surgeon at MGH earned approximately $1.9 million in one year at least, in part, because of routinely conducting concurrent surgeries.

129. Concurrently running multiple surgical rooms under the name (and the billing) of a single attending physician has substantially enriched MGH and certain orthopedic surgeons at the expense of federal and state health care programs.

F. DEFENDANTS' MEDICARE AND MEDICAID VIOLATIONS ARE MATERIAL

131. The expectation that critical surgeries are performed by fully credentialed and qualified physicians and that patients are fully informed as to all material elements of their surgeries is at the very core of the regulatory scheme. Violation of these requirements is material as that term is defined in the federal and state False Claims Acts and interpreted by the courts.

132. The centrality of these regulations is underscored, not only by their inclusion as a condition of participation and prerequisite for reimbursement, but by extensive interpretive

guidelines issued by CMS. For example, CMS was not content to leave limitations on concurrent surgeries set forth in 42 C.F.R. § 415.170 and 42 C.F.R. § 415.172(a) open to interpretation by MGH and other hospitals or providers. Rather, CMS provided extensive guidance on the responsibilities of teaching physicians, explaining what surgical practices are and are not permissible for overlapping surgeries. *See supra* ¶¶ 32-51. Massachusetts did the same. *See supra* ¶¶ 52-56. Defendants failed to adhere to this guidance.

133. Likewise, CMS emphasized the materiality of appropriate record-keeping by providing detailed guidance on documentation (*supra* ¶¶ 47-50). Appropriate documentation is critical as it helps ensure substantive compliance and allow detection of non-compliance with the law when conducting overlapping surgeries. Similarly, CMS adopted interpretive guidelines setting forth the contours of informed consent, and codes of medical ethics have long warned that concurrent surgeries, in the manner conducted by defendants, are unethical.

134. Materiality is further underscored by the Government's consistent action to punish and deter the conduct at issue. As HHS personnel recently confirmed in the context of a Congressional investigation, HHS Office of Inspector General ("HHS OIG") extensively audited billing practices at teaching hospitals in the past, and investigated allegations of whistleblowers related to such practices. Indeed, between 1995 and 2004, HHS OIG reported that 36 teaching hospitals settled False Claims Act or other similar cases related to these audits and investigations between 1995 and 2004, for amounts in excess of $225 million.

135. There have been at least 9 additional settlements by teaching hospitals involving similar issues in more recent years. For example, in 2016, the Department of Justice entered into a $2.5 million settlement with the University of Pittsburgh Medical Center (UPMC). Allegations

included that some neurosurgeons submitted claims to Medicare without participating in or supervising surgeries to the extent required.

136. No federal or state government payer has paid claims with actual knowledge that Defendants violated governing regulations and conditions of payment or participation. As the First Circuit has stated, "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103 (1st Cir. 2016). As detailed herein, Defendants have acted to conceal the nature of their concurrent surgeries from regulators, patients, and the public at large.

VI. COUNTS

COUNT I

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)[33]

137. All of the preceding allegations are incorporated herein.

138. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

139. By virtue of the conduct described above, Defendants knowingly caused to be presented to Medicare, Medicaid, and other Government funded health insurance programs false or fraudulent claims for the improper payment or approval of claims for: concurrent and/or overlapping surgeries, which did not comply with Medicare and Medicaid rules; concurrent or overlapping surgeries, which were not properly documented; concurrent and/or overlapping surgeries where unreasonable and unnecessary anesthesia was provided to patients; and concurrent and/or overlapping surgeries where valid informed consent was not obtained.

[33] To the extent wrongdoing occurred prior to May 20, 2009, this amended complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, e.g. 31 U.S.C. § 3729(a)(1)(2006).

140. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

141. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT II

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)[34]

142. All of the preceding allegations are incorporated herein.

143. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

144. By virtue of the conduct described above, Defendants knowingly caused to be made or used false records or statements that caused false claims to be paid or approved by the United States government.

145. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT III

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(C)[35]

146. All of the preceding allegations are incorporated herein.

147. This is a claim for treble damages and civil penalties under the False Claims Act,

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[34] To the extent wrongdoing occurred prior to May 20, 2009, this amended complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, e.g. 31 U.S.C. § 3729(a)(2).

[35] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, e.g. 31 U.S.C. § 3729(a)(3).

31 U.S.C. § 3729(a)(1)(C).

148. Defendants entered into a conspiracy or conspiracies through their member physicians, officers, and employees to defraud the United States by submitting and obtaining approval and payment for false and fraudulent claims for health care services provided to beneficiaries of federal health insurance programs, for among other things, concurrent and/or overlapping surgeries, which did not comply with Medicare and Medicaid rules; concurrent or overlapping surgeries, which were not properly documented; concurrent and/or overlapping surgeries where unreasonable and unnecessary anesthesia was provided to patients; and concurrent and/or overlapping surgeries where valid informed consent was not obtained.

149. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

150. By reason of these payments, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT IV

Federal False Claims Act, 31 U.S. C. § 3729(a)(1)(G)[36]

151. All of the preceding allegations are incorporated herein.

152. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

153. By virtue of the conduct described above, Defendants knowingly made, used or caused to be made or used false records or false statements that are material to an obligation to pay or transmit money to the Government.

[36] To the extent wrongdoing occurred prior to May 20, 2009, this Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, e.g. 31 U.S.C. § 3729(a)(7).

154. Because Defendants have failed to reimburse the federal government for sums it received unlawfully by virtue of the conduct described above, the United States has been damaged, and continues to be damaged, in a substantial amount.

COUNT V

MASSACHUSETTS FALSE CLAIMS LAW, M.G.L. c. 12 § 5B (a)(1)

155. All of the preceding allegations are incorporated herein.

156. This is a claim for treble damages, consequential damages, and civil penalties pursuant to the Massachusetts False Claims Law, M.G.L. c. 12 § 5B(a)(1).

157. By virtue of the conduct described above, Defendants knowingly caused to be presented to government funded health insurance programs, including Medicaid, false or fraudulent claims for the improper payment or approval of claims for: concurrent and/or overlapping surgeries, which did not comply with Medicare and Medicaid rules; concurrent or overlapping surgeries, which were not properly documented; concurrent and/or overlapping surgeries where unreasonable and unnecessary anesthesia was provided to patients; and concurrent and/or overlapping surgeries where valid informed consent was not obtained.

158. The Commonwealth of Massachusetts, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

159. By reason of these payments, the Commonwealth has been damaged, and continues to be damaged, in a substantial amount.

COUNT VI

MASSACHUSETTS FALSE CLAIMS LAW, M.G.L. c. 12, § 5B (a)(2)

160. All of the preceding allegations are incorporated herein.

161. This is a claim for treble damages, consequential damages, and civil penalties pursuant to the Massachusetts False Claims Law, M.G.L. c. 12 § 5B(a)(2).

162. By virtue of the conduct described above, Defendants knowingly caused to be made or used false records or statements that caused false claims to be paid or approved by the Commonwealth of Massachusetts.

163. The Commonwealth of Massachusetts, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

164. By reason of these payments, the Commonwealth has been damaged, and continues to be damaged, in a substantial amount.

COUNT VII

MASSACHUSETTS FALSE CLAIMS LAW, M.G.L. 12, § 5B (a)(3)

165. All of the preceding allegations are incorporated herein.

166. This is a claim for treble damages, consequential damages, and civil penalties pursuant to the Massachusetts False Claims Law, M.G.L. c. 12 § 5B(a)(3).

167. Defendants entered into a conspiracy or conspiracies through their member physicians, officers, and employees to defraud the Commonwealth of Massachusetts by submitting and obtaining approval and payment for false and fraudulent claims for health care services provided to beneficiaries of state health insurance programs, for among other things, concurrent and/or overlapping surgeries, which did not comply with Medicare and Medicaid rules; concurrent or overlapping surgeries, which were not properly documented; concurrent and/or overlapping surgeries where unreasonable and unnecessary anesthesia was provided to patients; and concurrent and/or overlapping surgeries where valid informed consent was not obtained.

168. The Commonwealth of Massachusetts, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

169. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

COUNT VIII

MASSACHUSETTS FALSE CLAIMS LAW, M.G.L. c. 12, § 5B (a)(9)

170. All of the preceding allegations are incorporated herein.

171. This is a claim for treble damages, consequential damages, and civil penalties under the pursuant to the Massachusetts False Claims Law, M.G.L. c. 12 § 5B (a)(9).

172. By virtue of the conduct described above, Defendants knowingly made, used or caused to be made or used false records or false statements that are material to an obligation to pay or transmit money to the government.

173. Because Defendants have failed to reimburse the Commonwealth of Massachusetts for sums it received unlawfully by virtue of the conduct described above, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

VII. PRAYER FOR RELIEF

WHEREFORE, for each of these claims, the *qui tam* Relator requests the following relief from each of the Defendants, jointly and severally, as to the federal and state claims:

A. Three times the amount of damages that the federal and state governments sustain because of the acts of Defendants;

B. A civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;[37]

C. A civil penalty of not less than $5,000 and not more than $10,000 per violation plus consequential damages for claims encompassed by the Massachusetts False Claim Law, pursuant to M.G.L. c. 12 § 5B(9);

[37] In June 30, 2016, the U.S. Department of Justice issued an interim final rule increasing civil penalties to $10,781 to $21,563 for violations that occurred after November 2, 2015. See 81 F.R. 42491.

D. The Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and M.G.L. c. 12 § 5F(1) for collecting the civil penalties and damages;

E. The Relator be awarded reasonable attorneys' fees and costs pursuant 31 U.S.C.§ 3730(d) and M.G.L. c. 12 § 5F (3);

F. Interest; and

G. Such further relief as the Court deems just and proper.

VIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: June 7, 2017

Respectfully submitted,

Relator
Lisa Wollman, M.D.

By her attorneys,

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*Admitted *pro hac vice*

CERTIFICATE OF SERVICE

I hereby certify that a copy of the Amended Complaint was served upon the following persons, this 7th day of June, 2017 via the means identified below.

Laura R. Studen

VIA CM/ECF

The United States of America	
United States Attorney General Jeff Sessions United States Department of Justice 950 Pennsylvania Ave., N.W. Washington, DC 20530 Sonya A. Rao, AUSA Abraham R. George, AUSA United States Attorney for the District of Massachusetts John Joseph Moakley U.S. Courthouse 1 Courthouse Way, Suite 9200 Boston, MA 02210	Ms. Joyce R. Branda Deputy Director, Commercial Litigation Branch Fraud Section U.S. Department of Justice Ben Franklin Station 950 Pennsylvania Avenue P.O. Box 261 Washington, D.C. 20530

Commonwealth of Massachusetts	
Attorney General Maura Healey c/o Amy Crafts, AAG Office of the Attorney General One Ashburton Place Boston, MA 02108-1698 (617) 727-2200 (617) 727-3251 (fax)	

VIA HAND DELIVERY ON AGENT FOR SERVICE OF PROCESS

Defendants	
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4843-8005-6906.1